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NEWS	3	Feb 1	Addition of Machine-Translated Abstracts to CAplus
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NEWS	9	Feb 28	Patent Information Now Searchable in CAOLD
NEWS	10	Mar 1	New IMSDIRECTORY Provides Pharma Company Details
NEWS	11	Mar 20	INPADOC: PRODUCER WARNING ABOUT DATA DELAYS
NEWS	12	Mar 22	NEW FEATURES IN INPADOC - RANGE SEARCHING AND NEW SDI/UPDATE SEARCH FIELD

NEWS EXPRESS	FREE UPGRADE 5.0C NOW AVAILABLE
NEWS HOURS	STN Operating Hours Plus Help Desk Availability
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COST IN U.S. DOLLARS	SINCE FILE ENTRY	TOTAL SESSION
FULL ESTIMATED COST	0.15	0.15

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=> s viagra/cn

L1             1 VIAGRA/CN

=> s sildenafil?/cn

L2             2 SILDENAFIL?/CN

=> file medline, hcaplus, uspatfull

COST IN U.S. DOLLARS                                SINCE FILE      TOTAL
                                                       ENTRY    SESSION
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FILE 'MEDLINE' ENTERED AT 14:40:46 ON 26 MAR 2000

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=> s l1 or l2

L3           445 L1 OR L2

=> s ed or eerecti? or impoten?

L4        228938 ED OR EERECTI? OR IMPOTEN?

=> s ed or erecti? or impoten?

L5        246668 ED OR ERECTI? OR IMPOTEN?

=> s spine or spinal or paraly?

L6        267236 SPINE OR SPINAL OR PARALY?

=> s l3 and l5

L7           345 L3 AND L5

=> s l7 and l6

L8            16 L7 AND L6

=> dup rem l8

PROCESSING COMPLETED FOR L8
L9            12 DUP REM L8 (4 DUPLICATES REMOVED)

=> d bib,ab,kwic l9 1-12
```

L9 ANSWER 1 OF 12 USPATFULL
AN 2000:31420 USPATFULL
TI Local administration of phosphodiesterase inhibitors for the treatment of **erectile** dysfunction
IN Doherty, Jr., Paul C., Cupertino, CA, United States
Place, Virgil A., Kawaihae, HI, United States
Smith, William L., Mahwah, NJ, United States
PA Vivus, Inc., Mountain View, CA, United States (U.S. corporation)
PI US 6037346 20000314
AI US 1998-181070 19981027 (9)
RLI Continuation-in-part of Ser. No. US 1997-958816, filed on 28 Oct 1997, now abandoned
DT Utility
EXNAM Primary Examiner: Reamer, James H.
LREP Reed, Dianne E.Reed & Associates
CLMN Number of Claims: 94
ECL Exemplary Claim: 1,23
DRWN 1 Drawing Figure(s); 1 Drawing Page(s)
LN.CNT 1331
CAS INDEXING IS AVAILABLE FOR THIS PATENT.
AB A method is provided for treating **erectile** dysfunction in a mammalian male individual. The method involves the local administration of a phosphodiesterase inhibitor or a pharmaceutically acceptable salt, ester, amide or derivative thereof within the context of an effective dosing regimen. A preferred mode of administration is transurethral. Pharmaceutical formulations and kits are provided as well.
TI Local administration of phosphodiesterase inhibitors for the treatment of **erectile** dysfunction
AB A method is provided for treating **erectile** dysfunction in a mammalian male individual. The method involves the local administration of a phosphodiesterase inhibitor or a pharmaceutically acceptable. . .
SUMM This invention relates generally to methods and pharmaceutical compositions for treating **erectile** dysfunction; more particularly, the invention relates to local administration of phosphodiesterase inhibitors to treat **erectile** dysfunction.
SUMM **Impotence** is the consistent inability to achieve or sustain an **erection** of sufficient rigidity for sexual intercourse. It has recently been estimated that approximately 10 million American men are **impotent** (R. Shabsigh et al., "Evaluation of **Erectile Impotence**," Urology 32:83-90 (1988); W. L. Furlow, "Prevalence of **Impotence** in the United States," Med Aspects Hum. Sex. 19:13-6 (1985)). **Impotence** is recognized to be an age-dependent disorder, with an incidence of 1.9 percent at 40 years of age and 25. . . Male; A. C. Kinsey et al., eds., Philadelphia, Pa.: W. B. Saunders, 218-262 (1948)). In 1985 in the United States, **impotence** accounted for more than several hundred thousand outpatient visits to physicians Rational Center for Health Statistics, National Hospital Discharge Survey,. . .
SUMM A number of causes of **impotence** have been identified, including vasculogenic, neurogenic, endocrinologic and psychogenic. Vasculogenic **impotence**, which is caused by alterations in the flow of blood to and from the penis, is thought to be the most frequent organic cause of **impotence**. Common risk factors for vasculogenic **impotence** include hypertension, diabetes, cigarette smoking, pelvic trauma, and the like. Neurogenic **impotence** is associated with **spinal**-cord injury, multiple sclerosis, peripheral neuropathy caused by diabetes or alcoholism and severance of the autonomic nerve supply to the penis consequent to prostate surgery. **Erectile** dysfunction is also associated with disturbances in endocrine function resulting in low circulating testosterone levels and elevated prolactin levels.
SUMM **Impotence** can also be a side effect of various classes of drugs, in particular, those that interfere with central neuroendocrine

control. . . or local neurovascular control of penile smooth muscle. Krane et al., New England Journal of Medicine 321: 1648 (1989). Penile **erection** requires (1) dilation of the arteries that regulate blood flow to the lacunae of the corpora cavernosum, (2) relaxation of. . .

SUMM . . . vasoactive substances such as vasoactive intestinal polypeptide (VIP), prostanoids, endothelin and nitric oxide. High sympathetic tone (noradrenergic) is implicated in **erectile** dysfunction, and, in some patients, the disorder can be successfully treated with noradrenergic receptor antagonists. See, e.g., Krane et al.,. . .

SUMM There is also evidence that dopaminergic mechanisms are involved in **erectile** function. For example, pharmacologic agents that elevate the level of brain dopamine or stimulate brain dopamine receptors increase sexual activity. . .

SUMM . . . Hyppa et al., Acta Neurologic Scand. 46:223 (Supp. 43, 1970)). Specific dopamine agonists have been studied for their effects on **erectile** function. Apomorphine, (n-propyl)norapo-morphine, bromocryptine, amantidine, fenfluramine, L-DOPA and various other pharmacological activators of central dopaminergic receptors have been found to increase episodes of penile **erection** in male rats (Benassi-Benelli et al., Arch. int. Pharmacodyn. 242:241 (1979); Poggioli et al., Riv. di Farm. & Terap. 9:213. . .

SUMM The currently available dopamine agonists, with few exceptions, have found limited use in the treatment of **erectile** dysfunction because of their peripheral side effects. These effects include nausea and vomiting, postural hypotension, arrhythmias, tachycardia, dysphoria, psychosis, hallucinations, drowsiness and dysidnesias (See, e.g., Martindale The Extra Pharmacopoeia, 31st **Ed**., pages 1151-1168).

SUMM Other pharmaceutical methods for treating **erectile** dysfunction have also proved to be problematic. For example, with Viagra.RTM., the most recently introduced oral drug therapy, not only. . .

SUMM . . . herein provides a means to avoid the above-mentioned problems encountered with the systemic administration of pharmacologically active agents to treat **erectile** dysfunction. Specifically, the invention relates to methods and formulations for effectively treating **erectile** dysfunction by locally administering a selected active agent, wherein the active agent is an inhibitor of a phosphodiesterase.

SUMM . . . messenger nucleotides, cyclic adenosine monophosphate (cAMP), and cyclic guanosine monophosphate (cGMP) (see, e.g., Doherty, "Oral, Transdermal, and Transurethral Therapies for **Erectile** Dysfunction" in Male Infertility and Dysfunction, Hellstrom, **ed**., Chapter 34 (New York, N.Y.: Springer-VerlagHellstrom, 1997)). Numerous phosphodiesterase inhibitors have previously been described in the literature for a variety. . . 34). Oral and parenteral administration of phosphodiesterase inhibitors, as alluded to above, have also been suggested for the treatment of **erectile** dysfunction (Doherty, supra; see also PCT Publication Nos. WO 96/16644, and WO 94/28902). The phosphodiesterases have been classified into seven. . .

SUMM The following documents are of interest insofar as they relate to the treatment of **erectile** dysfunction by delivering pharmacologically active agents locally to the penis:

SUMM . . . injection of vasodilator drugs into the corpora cavernosa of the penis to dilate the arteries that supply blood to the **erectile** tissues, thereby inducing an **erection**;

SUMM . . . direct injection of a drug into the corpora cavernosa, by topical drug administration or transurethral drug administration, for inhibiting penile **erection** due to priapism and for treating urinary incontinence;

SUMM . . . the intracavernosal injection of papaverine (a smooth muscle relaxant), phenoxybenzamine or phentolamine (.alpha.-receptor blockers)

and a phentolamine-papaverine mixture to treat **erectile** dysfunction; and

SUMM . . . et al., and U.S. Pat. Nos. 5,242,391, 5,474,535, 5,686,093 and 5,773,020 to Place et al. relate to the treatment of **erectile** dysfunction by delivery of a vasoactive agent into the male urethra.

SUMM The invention, as noted above, is directed to local administration of pharmacologically active agents to treat **erectile** dysfunction. The agents are preferably, although not necessarily, Type V phosphodiesterase inhibitors. Surprisingly, it has now been found by the inventors herein that local administration of these phosphodiesterase inhibitors as disclosed herein is highly effective in treating **erectile** dysfunction, particularly vasculogenic **impotence**. Local administration of phosphodiesterase inhibitors, and transurethral drug administration in particular, generally enables use of a lower drug dosage, avoids. . . administered medications an individual may be taking. The local administration of phosphodiesterase inhibitors, particularly Type V phosphodiesterase inhibitors, to treat **erectile** dysfunction, accordingly represents an important advance in the treatment of **impotence** and other **erectile** disorders.

SUMM . . . primary object of the invention to address the above-described need in the art by providing a novel method for treating **erectile** dysfunction by locally administering an effective amount of a selected phosphodiesterase inhibitor to an individual in need of such therapy.

SUMM In a first aspect of the invention, a method is provided for treating an individual prone to **erectile** dysfunction, particularly vasculogenic **erectile** dysfunction, the method comprising locally administering to the individual a pharmaceutical formulation containing a phosphodiesterase inhibitor. Administration of the pharmaceutical. . . carried out within the context of a predetermined dosing regimen such that the agent is effective in the treatment of **erectile** dysfunction. The method is especially useful in the treatment of vasculogenic **impotence**, although other types of **erectile** dysfunction may also be treated using the present formulations. Drug delivery is preferably effected transurethrally, but the drug may also. . .

SUMM In another aspect of the invention, a pharmaceutical formulation is provided for carrying out the present method for treating **erectile** dysfunction. The pharmaceutical formulation comprises an effective amount of a phosphodiesterase inhibitor, a carrier or vehicle preferably suitable for the. . .

SUMM . . . formulation during storage and prior to use; and instructions for carrying out drug administration in a manner effective to treat **erectile** dysfunction.

DETD The term "**erectile** dysfunction" is intended to include any and all types of **erectile** dysfunction, including: vasculogenic, neurogenic, endocrinologic and psychogenic **impotence** ("**impotence**" is used here in its broadest sense to indicate an inability a periodic or consistent inability to achieve or sustain an **erection** of sufficient rigidity for sexual intercourse; see U.S. Pat. No. 5,242,391 to Place et al., cited supra); Peyronie's syndrome; priapism;. . .

DETD . . . of the occurrence of symptoms and/or their underlying cause, and improvement or remediaton of damage. The present method of "treating" **erectile** dysfunction, as the term is used herein, thus encompasses both prevention of the disorder in a predisposed individual and treatment. . .

DETD . . . is meant a nontoxic but sufficient amount of the drug or agent to provide the desired effect, i.e., treatment of **erectile** dysfunction.

DETD Active Agents for Treatment of **Erectile** Dysfunction:

DETD . . . to carry out the method of the invention, a selected phosphodiesterase inhibitor is locally administered to an individual prone to **erectile** dysfunction.

DETD . . . art of synthetic organic chemistry and described, for example, by J. March, Advanced Organic Chemistry; Reactions, Mechanisms and Structure, 4th **Ed**. (New York: Wiley-Interscience, 1992). For example, acid addition salts are prepared from the free base using conventional methodology, and involves. . .

DETD The active agent is administered locally to treat **erectile** dysfunction, and is accordingly administered in a pharmaceutical formulation suitable for local administration.

DETD . . . as described in the pertinent literature and pharmaceutical texts. See, for example, Remington: The Science and Practice of Pharmacy, 19th **Ed**. (Easton, Pa.: Mack Publishing Co., 1995), which discloses typical methods of preparing pharmaceutical compositions in the form of urethral suppositories.. . .

DETD . . . control device such as that described in PCT Publication No. WO 97/47260, entitled "Venous Flow Control Element for Maintaining Penile **Erection**." Preferred devices are formed from a length of flexible tubing having an integral fastening means, so as to provide for. . . it effectively enhances retention of blood within the penis without substantially obstructing arterial inflow or becoming too constrictive during the **erectile** process. Use of the VFC device also enables enhanced effectiveness of local drug therapy, in that the active agent is retained within the penis, allowing movement into the corpus cavernosa. This produces smooth muscle response and a consistent **erectile** response. In this embodiment, a kit will include the venous flow control device in addition to the components noted above,. . .

DETD The pharmaceutical preparations of Examples 1 and 2 can be used to treat **erectile** dysfunction in individuals in which the dysfunction is associated, for example, vascular insufficiency. Dosage may be adjusted using the methodology. . . Example 3. In all instances the individuals are expected to respond positively, although variations in the intensity and duration of **erection** may be observed depending on dose, formulation and environment. Generally, between approximately 20 and 90 minutes following drug administration, it is expected that an **erection** may be achieved.

DETD In this experiment, zaprinast, a Type V phosphodiesterase inhibitor, was evaluated for its capability to induce **erections** in the anesthetized male cat. Adult male cats (3.5 to 5.0 kg) were initially sedated with ketamine and then anesthetized. . . mm, respectively). These results suggest that a selective Type V phosphodiesterase inhibitor, when administered locally, can induce significant increases in **erectile** response in a mammalian male. The same or greater effects are expected upon administration of a urethral suppository.

CLM What is claimed is:

1. A method for treating **erectile** dysfunction in a male individual, comprising locally administering to the individual an effective amount of a pharmaceutical composition consisting essentially.

. .

13. The method of claim 1, wherein the **erectile** dysfunction is vasculogenic **impotence**.

18. A pharmaceutical formulation for treating **erectile** dysfunction in an individual, comprising a urethral dosage form of a phosphodiesterase inhibitor, a carrier suitable for transurethral drug administration,. . .

20. A pharmaceutical formulation for treating **erectile** dysfunction in an individual comprising a sterile liquid composition

suitable for intracavernosal administration containing a therapeutically effective amount of a. . .

21. A pharmaceutical formulation for treating **erectile** dysfunction in an individual, comprising a topical or transdermal composition containing a therapeutically effective amount of a phosphodiesterase inhibitor and. . .

23. A kit for treating **erectile** dysfunction in an individual, comprising: a urethral dosage form of a Type V, cGMP-specific phosphodiesterase inhibitor or a pharmaceutically acceptable. . . for using the drug delivery means to administer the drug within the context of a dosing regimen effective to treat **erectile** dysfunction.

86. A method for treating **erectile** dysfunction in a male individual, comprising administering to the individual a pharmaceutical composition comprising a therapeutically effective amount of: (a). . .

IT 58-32-2, Dipyridamole 69-89-6D, Xanthine, derivs. 120-73-0D, Purine, derivs. 253-82-7D, Quinazoline, derivs. 289-95-2D, Pyrimidine, derivs. 37762-06-4, Zaprinast 51022-77-6, Etazolate 51022-77-6D, Etazolate, esters and analogs 56739-21-0, Nitraquazone 56739-21-0D, Nitraquazone, esters and analogs 57076-71-8, Denbufylline 61413-54-5, Rolipram 61413-54-5D, Rolipram, esters and analogs 66327-51-3, Furazlocillin 79030-08-3D, Griseolic acid, derivs. 120223-30-5, EMD54622 120223-30-5D, EMD54622, esters and analogs 136145-07-8, LAS-31025 136145-07-8D, LAS-31025, esters and analogs 139145-27-0 **139755-83-2**, Sildenafil 147676-63-9 150452-19-0 167298-74-0 184147-55-5 190281-17-5D, Pyrazolopyrimidinone, derivs. 224157-99-7
(phosphodiesterase inhibitor local administration for treatment of erectile dysfunction)

L9 ANSWER 2 OF 12 MEDLINE
AN 1999334975 MEDLINE
DN 99334975
TI **Erectile** dysfunction in spina bifida is treatable [letter].
AU Palmer J S; Kaplan W E; Firlit C F
SO LANCET, (1999 Jul 10) 354 (9173) 125-6.
Journal code: L0S. ISSN: 0140-6736.
CY ENGLAND: United Kingdom
DT (CLINICAL TRIAL)
Letter
(RANDOMIZED CONTROLLED TRIAL)
LA English
FS Abridged Index Medicus Journals; Priority Journals; Cancer Journals
EM 199910
EW 19991001
AB We undertook a prospective, blinded, randomised, placebo-controlled, dose escalation, crossover study that showed that **erectile** dysfunction in spina bifida is medically treatable, specifically with sildenafil citrate.
TI **Erectile** dysfunction in spina bifida is treatable [letter].
AB We undertook a prospective, blinded, randomised, placebo-controlled, dose escalation, crossover study that showed that **erectile** dysfunction in spina bifida is medically treatable, specifically with sildenafil citrate.
CT Check Tags: Human; Support, Non-U.S. Gov't
Adult
Analysis of Variance
Cross-Over Studies
***Impotence: DT, drug therapy**
Impotence: ET, etiology
*Phosphodiesterase Inhibitors: TU, therapeutic use
*Piperazines: TU, therapeutic use

Single-Blind Method
*Spinal Dysraphism: CO, complications
RN 139755-83-2 (sildenafil)

L9 ANSWER 3 OF 12 HCAPLUS COPYRIGHT 2000 ACS
AN 1999:690785 HCAPLUS
DN 131:281606
TI Method of treating **impotence** due to **spinal** cord injury with sildenafil or other cGMP phosphodiesterase inhibitor
IN Maytom, Murray Craig; Osterloh, Ian Howard
PA Pfizer Ltd., UK; Pfizer Research and Development Company, N.V./S.A.
SO Eur. Pat. Appl., 7 pp.
CODEN: EPXXDW
DT Patent
LA English
FAN.CNT 1

	PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
PI	EP 951908	A2	19991027	EP 1999-301085	19990215
	R: AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LI, LU, NL, SE, MC, PT, IE, SI, LT, LV, FI, RO				
	JP 11315025	A2	19991116	JP 1999-43205	19990222
	AU 9918390	A1	19990909	AU 1999-18390	19990223
PRAI	US 1998-75580		19980223		

OS MARPAT 131:281606
AB A class of cGMP phosphodiesterase inhibitors, including sildenafil and pharmaceutically acceptable salts thereof, is disclosed for use in the treatment of sexual dysfunction in male and female animals, esp. humans, with a **spinal** cord injury. The invention can be used to treat sexual dysfunction in male animals that exhibit essentially no residual penile function.
TI Method of treating **impotence** due to **spinal** cord injury with sildenafil or other cGMP phosphodiesterase inhibitor
AB . . . thereof, is disclosed for use in the treatment of sexual dysfunction in male and female animals, esp. humans, with a **spinal** cord injury. The invention can be used to treat sexual dysfunction in male animals that exhibit essentially no residual penile. . .
ST cGMP phosphodiesterase inhibitor sexual dysfunction; sildenafil sexual dysfunction **spinal** cord injury; **erectile** dysfunction **spinal** cord injury sildenafil
IT Sexual behavior
(disorder; sildenafil or other cGMP phosphodiesterase inhibitor for treatment of sexual dysfunction in animal with **spinal** cord injury)
IT Sexual behavior
(**impotence**; sildenafil or other cGMP phosphodiesterase inhibitor for treatment of sexual dysfunction in animal with **spinal** cord injury)
IT **Spinal** cord
(injury; sildenafil or other cGMP phosphodiesterase inhibitor for treatment of sexual dysfunction in animal with **spinal** cord injury)
IT 9068-52-4, CGMP phosphodiesterase
RL: BSU (Biological study, unclassified); BIOL (Biological study)
(inhibitors; sildenafil or other cGMP phosphodiesterase inhibitor for treatment of sexual dysfunction in animal with **spinal** cord injury)
IT **139755-83-2 171599-83-0**, Sildenafil citrate
RL: BAC (Biological activity or effector, except adverse); THU (Therapeutic use); BIOL (Biological study); USES (Uses)
(sildenafil or other cGMP phosphodiesterase inhibitor for treatment of sexual dysfunction in animal with **spinal** cord injury)

L9 ANSWER 4 OF 12 MEDLINE DUPLICATE 1
AN 1999325995 MEDLINE

DN 99325995
TI Sildenafil: a review of its use in **erectile** dysfunction.
AU Langtry H D; Markham A
CS Adis International Limited, Mairangi Bay, Auckland, New Zealand.
SO DRUGS, (1999 Jun) 57 (6) 967-89. Ref: 80
Journal code: EC2. ISSN: 0012-6667.
CY New Zealand
DT Journal; Article; (JOURNAL ARTICLE)
General Review; (REVIEW)
(REVIEW, ACADEMIC)
LA English
FS Priority Journals
EM 199911
EW 19991102
AB Sildenafil is an oral therapy for **erectile** dysfunction of a broad range of causes. By selectively inhibiting phosphodiesterase type 5, it allows corpus cavernosum smooth muscle to relax, potentiating **erections** during sexual stimulation. Blood pressure is reduced transiently by sildenafil, but more marked hypotension may occur during concurrent administration of sildenafil and organic nitrates; this combination is contraindicated. Sildenafil is rapidly absorbed, with dose-proportional peak plasma concentrations within 1 hour of administration. The elimination half-life is 3 to 5 hours. Dosages usually begin at 50mg taken when needed =1 hour before sexual activity no more than once daily. The maximum dose is 100mg when needed once daily and lower doses (e.g. 25mg) may be used in elderly patients and those with hepatic or renal impairment or receiving cytochrome P450 enzyme CYP3A4 inhibitors, such as ritonavir, saquinavir, ketoconazole, erythromycin or cimetidine. More than 3000 patients with **erectile** dysfunction of organic (e.g. diabetes or **spinal** cord injury), psychogenic or mixed origin received sildenafil 5 to 100mg or placebo in fixed- or titrated-dose trials. Sildenafil was associated with dose-related improvements in the frequency, hardness and duration of **erections** and in patients' abilities to achieve and maintain **erections** adequate for successful sexual intercourse. In titrated-dose trials, the most commonly effective doses were 50 or 100mg, although lower doses were effective in some patients. Sildenafil was significantly more effective than placebo in **erectile** dysfunction of all tested causes. The efficacy of sildenafil was not affected by patient age (> or < or =65 years) or by antihypertensive or antidepressant medications. The drug was effective in patients with severe **erectile** dysfunction. Efficacy was maintained in long term (1-year) studies. Sildenafil also appears to improve the quality of life of both patients and their sexual partners. Common adverse events associated with sildenafil were transient and mild or moderate and included headache, flushing, dyspepsia, nasal congestion and abnormal vision. Tolerability was maintained in long term (< or =1 year) studies. No serious sildenafil-related adverse events occurred in clinical trials; cardiovascular events seen in postmarketing surveillance generally occurred in patients with other known risk factors.
CONCLUSIONS:
Sildenafil is an effective oral treatment in men with **erectile** dysfunction. It was significantly superior to placebo in improving **erections** and allowing successful penetrative sexual intercourse. Although its place in disease management is still emerging and there are contraindications to its use, if preliminary positive reports are confirmed, sildenafil will be the pre-eminent first-line therapy for **erectile** dysfunction.
TI Sildenafil: a review of its use in **erectile** dysfunction.
AB Sildenafil is an oral therapy for **erectile** dysfunction of a broad range of causes. By selectively inhibiting phosphodiesterase type 5, it allows corpus cavernosum smooth muscle to relax, potentiating **erections** during sexual stimulation. Blood pressure is reduced

transiently by sildenafil, but more marked hypotension may occur during concurrent administration of. . . or receiving cytochrome P450 enzyme CYP3A4 inhibitors, such as ritonavir, saquinavir, ketoconazole, erythromycin or cimetidine. More than 3000 patients with **erectile** dysfunction of organic (e.g. diabetes or **spinal** cord injury), psychogenic or mixed origin received sildenafil 5 to 100mg or placebo in fixed- or titrated-dose trials. Sildenafil was associated with dose-related improvements in the frequency, hardness and duration of **erections** and in patients' abilities to achieve and maintain **erections** adequate for successful sexual intercourse. In titrated-dose trials, the most commonly effective doses were 50 or 100mg, although lower doses were effective in some patients. Sildenafil was significantly more effective than placebo in **erectile** dysfunction of all tested causes. The efficacy of sildenafil was not affected by patient age (> or < or =65 years) or by antihypertensive or antidepressant medications. The drug was effective in patients with severe **erectile** dysfunction. Efficacy was maintained in long term (1-year) studies. Sildenafil also appears to improve the quality of life of both. . . surveillance generally occurred in patients with other known risk factors. CONCLUSIONS: Sildenafil is an effective oral treatment in men with **erectile** dysfunction. It was significantly superior to placebo in improving **erections** and allowing successful penetrative sexual intercourse. Although its place in disease management is still emerging and there are contraindications to its use, if preliminary positive reports are confirmed, sildenafil will be the pre-eminent first-line therapy for **erectile** dysfunction.

CT Check Tags: Human; Male
Clinical Trials
Drug Interactions
***Impotence: DT, drug therapy**
Phosphodiesterase Inhibitors: AE, adverse effects
Phosphodiesterase Inhibitors: PD, pharmacology
*Phosphodiesterase Inhibitors: TU, therapeutic use
*Piperazines: TU, therapeutic. . .

RN **139755-83-2 (sildenafil)**

L9 ANSWER 5 OF 12 HCAPLUS COPYRIGHT 2000 ACS
AN 2000:15560 HCAPLUS
DN 132:59075
TI Sildenafil citrate to treat **erectile** dysfunction in the spina bifida male
AU Palmer, Jeffrey S.; Kaplan, William E.; Firlit, Casimir F.
CS Division of Urology, Children's Memorial Medical Center, Northwestern University Medical School, Chicago, IL, USA
SO Surg. Forum (1999), 50, 712-713
CODEN: SUFOAX; ISSN: 0071-8041
PB American College of Surgeons
DT Journal
LA English
AB Sildenafil citrate (25 or 50 mg) dose-dependently improved **erectile** function in men with spina bifida.
TI Sildenafil citrate to treat **erectile** dysfunction in the spina bifida male
AB Sildenafil citrate (25 or 50 mg) dose-dependently improved **erectile** function in men with spina bifida.
ST sildenafil **erectile** dysfunction spina bifida; **impotence** spina bifida sildenafil
IT Sexual behavior
(**impotence**; sildenafil citrate treatment of **erectile** dysfunction in men with spina bifida)
IT **Spinal** column
(spina bifida; sildenafil citrate treatment of **erectile** dysfunction in men with spina bifida)

IT **171599-83-0**, Sildenafil citrate
RL: BAC (Biological activity or effector, except adverse); THU (Therapeutic use); BIOL (Biological study); USES (Uses)
(sildenafil citrate treatment of **erectile** dysfunction in men with spina bifida)

L9 ANSWER 6 OF 12 MEDLINE
AN 1999163632 MEDLINE
DN 99163632
TI A two-part pilot study of sildenafil (VIAGRA) in men with **erectile** dysfunction caused by **spinal** cord injury.
AU Maytom M C; Derry F A; Dinsmore W W; Glass C A; Smith M D; Orr M; Osterloh I H
CS Pfizer Central Research, Sandwich, UK.
SO SPINAL CORD, (1999 Feb) 37 (2) 110-6.
Journal code: CKK. ISSN: 1362-4393.
CY ENGLAND: United Kingdom
DT (CLINICAL TRIAL)
Journal; Article; (JOURNAL ARTICLE)
(MULTICENTER STUDY)
(RANDOMIZED CONTROLLED TRIAL)
LA English
FS Priority Journals
EM 199907
EW 19990702
AB STUDY DESIGN: This was a two-part pilot study in men with **erectile** dysfunction (**ED**) due to **spinal** cord injury (SCI: cord level range T6-L5). Part I was a randomised, double-blind, two-way cross-over study comparing a single dose of sildenafil 50 mg or placebo. Part II was a randomised, double-blind, parallel-group evaluation of sildenafil 50 mg or placebo, taken as required (not more than once daily) approximately 1 h prior to sexual activity, over a period of 28 days. OBJECTIVES: To assay the efficacy and safety of sildenafil 50 mg and placebo. SETTING: Clinic- and home-based assessments in the United Kingdom. METHODS: A total of 27 subjects who were able to achieve at least a grade 2 **erection** (hard, but not hard enough for penetration) in response to penile vibratory stimulation (PVS) were recruited. In Part I, the reflexogenic response of the penis to PVS was evaluated in the clinic while in Part II, the response to treatment was assessed in the home (global efficacy. questionniare, diary). RESULTS: In Part I, 17/26 (65%) subjects had **erections** of >60% rigidity at the penile base (median duration 3.5 min) after sildenafil compared with 2/26 (8%) (median duration 0 min) alter placebo (P=0.0003). In Part II, 9/12 (75%) subjects on sildenafil and 1/14 (7%) subjects on placebo reported that the treatment had improved their **erections** (P<0.005), and 8/12 (67%) and 2/13 (15%) men, respectively, indicated that they wished to continue treatment (P<0.02). An analysis of diary data showed no difference between the groups with respect to the mean number of **erections** hard enough for penetration (P = 0.08). The mean proportion of attempts at sexual intercourse that were successful was 30 and 15%, respectively (P=0.21). Similarly, responses to the end-of-treatment questionnaire indicated that there were no significant differences between the groups with respect to the frequency of **erections** hard enough for sexual intercourse (P=0.47) or that lasted as long as the subject would have liked (P=0.11). No subject discontinued sildenafil due to adverse events. CONCLUSION: Sildenafil is an effective, well-tolerated oral treatment for **ED** in SCI subjects.
TI A two-part pilot study of sildenafil (VIAGRA) in men with **erectile** dysfunction caused by **spinal** cord injury.
AB STUDY DESIGN: This was a two-part pilot study in men with **erectile** dysfunction (**ED**) due to **spinal** cord injury (SCI: cord

level range T6-L5). Part I was a randomised, double-blind, two-way cross-over study comparing a single dose. . . in the United Kingdom. METHODS: A total of 27 subjects who were able to achieve at least a grade 2 **erection** (hard, but not hard enough for penetration) in response to penile vibratory stimulation (PVS) were recruited. In Part I, the. . . response to treatment was assessed in the home (global efficacy. questionniare, diary). RESULTS: In Part I, 17/26 (65%) subjects had **erections** of >60% rigidity at the penile base (median duration 3.5 min) after sildenafil compared with 2/26 (8%) (median duration 0. . . Part II, 9/12 (75%) subjects on sildenafil and 1/14 (7%) subjects on placebo reported that the treatment had improved their **erections** (P<0.005), and 8/12 (67%) and 2/13 (15%) men, respectively, indicated that they wished to continue treatment (P<0.02). An analysis of diary data showed no difference between the groups with respect to the mean number of **erections** hard enough for penetration (P = 0.08). The mean proportion of attempts at sexual intercourse that were successful was 30. . . to the end-of-treatment questionnaire indicated that there were no significant differences between the groups with respect to the frequency of **erections** hard enough for sexual intercourse (P=0.47) or that lasted as long as the subject would have liked (P=0.11). No subject discontinued sildenafil due to adverse events. CONCLUSION: Sildenafil is an effective, well-tolerated oral treatment for **ED** in SCI subjects.

CT Check Tags: Human; Male; Support, Non-U.S. Gov't
Adult
Cross-Over Studies
Double-Blind Method
***Impotence: DT, drug therapy**
***Impotence: ET, etiology**
Middle Age
Phosphodiesterase Inhibitors: AE, adverse effects
*Phosphodiesterase Inhibitors: TU, therapeutic use
Pilot Projects
Piperazines: AE, adverse effects
*Piperazines: TU, therapeutic use
***Spinal Cord Injuries: CO, complications**
Treatment Outcome

RN **139755-83-2 (sildenafil)**

L9 ANSWER 7 OF 12 MEDLINE DUPLICATE 2
AN 2000128503 MEDLINE
DN 20128503
TI Sildenafil citrate (VIAGRA): a novel oral treatment for **erectile** dysfunction caused by traumatic **spinal** cord injury.
AU Giuliano F; Hultling C; el Masry W S; Luchner E; Stien R; Maytom M C; Orr M; Smith M D; Osterloh I H
CS Hopital de Bicetre, Paris, France.
SO INTERNATIONAL JOURNAL OF CLINICAL PRACTICE. SUPPLEMENT, (1999 Jun) 102 24-6.
Journal code: CW2. ISSN: 1368-504X.
CY ENGLAND: United Kingdom
DT (CLINICAL TRIAL)
Journal; Article; (JOURNAL ARTICLE)
(RANDOMIZED CONTROLLED TRIAL)
LA English
EM 200004
EW 20000404
TI Sildenafil citrate (VIAGRA): a novel oral treatment for **erectile** dysfunction caused by traumatic **spinal** cord injury.
CT Check Tags: Human; Male
Administration, Oral
Adult
Cross-Over Studies
Double-Blind Method

***Impotence: DT, drug therapy**
Impotence: ET, etiology
Middle Age
*Phosphodiesterase Inhibitors: AD, administration & dosage
*Piperazines: AD, administration & dosage
Spinal Cord Injuries: CO, complications
RN **139755-83-2 (sildenafil)**

L9 ANSWER 8 OF 12 MEDLINE
AN 2000128500 MEDLINE
DN 20128500
TI Partners' perceptions of the efficacy of sildenafil citrate (VIAGRA) in the treatment of **erectile** dysfunction.
AU Hultling C
CS Spinalis SCI Research Unit, Karolinska Institute, Stockholm, Sweden.
SO INTERNATIONAL JOURNAL OF CLINICAL PRACTICE. SUPPLEMENT, (1999 Jun) 102 16-8.
Journal code: CW2. ISSN: 1368-504X.
CY ENGLAND: United Kingdom
DT (CLINICAL TRIAL)
Journal; Article; (JOURNAL ARTICLE)
(RANDOMIZED CONTROLLED TRIAL)
LA English
EM 200004
EW 20000404
TI Partners' perceptions of the efficacy of sildenafil citrate (VIAGRA) in the treatment of **erectile** dysfunction.
CT Check Tags: Female; Human; Male
Adult
Aged
Aged, 80 and over
Cross-Over Studies
Double-Blind Method
***Impotence: DT, drug therapy**
Impotence: ET, etiology
Middle Age
***Penile Erection**
Perception
*Phosphodiesterase Inhibitors: AD, administration & dosage
*Piperazines: AD, administration & dosage
*Sexual Partners
Spinal Cord Injuries: CO, complications
RN **139755-83-2 (sildenafil)**

L9 ANSWER 9 OF 12 MEDLINE DUPLICATE 3
AN 1999328203 MEDLINE
DN 99328203
TI Randomized trial of sildenafil for the treatment of **erectile** dysfunction in **spinal** cord injury. Sildenafil Study Group.
AU Giuliano F; Hultling C; El Masry W S; Smith M D; Osterloh I H; Orr M; Maytom M
CS Service d'Urologie, AP-HP, CHU de Bicetre, Le Kremlin Bicetre, France.
SO ANNALS OF NEUROLOGY, (1999 Jul) 46 (1) 15-21.
Journal code: 6AE. ISSN: 0364-5134.
CY United States
DT (CLINICAL TRIAL)
Journal; Article; (JOURNAL ARTICLE)
(RANDOMIZED CONTROLLED TRIAL)
LA English
FS Priority Journals
EM 199910
EW 19991001
AB **Erectile** dysfunction is a common complication of **spinal** cord injury. This double-blind, placebo-controlled, two-way crossover study assessed the efficacy and safety of oral sildenafil in men with

erectile dysfunction caused by traumatic **spinal** cord injury. A total of 178 men (mean age, 38 years) received placebo or sildenafil 1 hour before sexual activity for 6 weeks; after a 2-week washout period, the men received the alternate treatment for 6 weeks. The 50-mg starting dose could be adjusted to 100 or 25 mg based on efficacy and tolerability. Efficacy was assessed by using global efficacy questions, the International Index of **Erectile** Function (IIEF), and a patient log of **erectile** activity. Of 143 men with residual **erectile** function at baseline, 111 (78%) reported improved **erections** and preferred sildenafil to placebo. For all men (including those who reported no residual **erectile** function at baseline), 127 of 168 (76%) reported improved **erections** and preferred sildenafil to placebo. For all men, 132 of 166 (80%) reported that sildenafil improved sexual intercourse compared with 17 of 166 men (10%) reporting improvement with placebo. IIEF questions assessing the ability to achieve and maintain **erections** and satisfaction with sexual intercourse demonstrated significant improvement with sildenafil. Sildenafil was well tolerated, with a low rate of discontinuation because of treatment-related adverse events (2% vs 1% for placebo). Oral sildenafil is an effective and well-tolerated treatment for **erectile** dysfunction caused by **spinal** cord injury.

TI Randomized trial of sildenafil for the treatment of **erectile** dysfunction in **spinal** cord injury. Sildenafil Study Group.

AB **Erectile** dysfunction is a common complication of **spinal** cord injury. This double-blind, placebo-controlled, two-way crossover study assessed the efficacy and safety of oral sildenafil in men with **erectile** dysfunction caused by traumatic **spinal** cord injury. A total of 178 men (mean age, 38 years) received placebo or sildenafil 1 hour before sexual activity. . . or 25 mg based on efficacy and tolerability. Efficacy was assessed by using global efficacy questions, the International Index of **Erectile** Function (IIEF), and a patient log of **erectile** activity. Of 143 men with residual **erectile** function at baseline, 111 (78%) reported improved **erections** and preferred sildenafil to placebo. For all men (including those who reported no residual **erectile** function at baseline), 127 of 168 (76%) reported improved **erections** and preferred sildenafil to placebo. For all men, 132 of 166 (80%) reported that sildenafil improved sexual intercourse compared with 17 of 166 men (10%) reporting improvement with placebo. IIEF questions assessing the ability to achieve and maintain **erections** and satisfaction with sexual intercourse demonstrated significant improvement with sildenafil. Sildenafil was well tolerated, with a low rate of discontinuation because of treatment-related adverse events (2% vs 1% for placebo). Oral sildenafil is an effective and well-tolerated treatment for **erectile** dysfunction caused by **spinal** cord injury.

CT Check Tags: Human; Male; Support, Non-U.S. Gov't
Administration, Oral
Cross-Over Studies
Double-Blind Method
***Impotence: DT, drug therapy**
Impotence: ET, etiology
Phosphodiesterase Inhibitors: AD, administration & dosage
Phosphodiesterase Inhibitors: AE, adverse effects
*Phosphodiesterase Inhibitors: TU, therapeutic use
Piperazines: AD, administration & dosage
Piperazines: AE, adverse effects
*Piperazines: TU, therapeutic use
***Spinal Cord Injuries: CO, complications**

RN **139755-83-2 (sildenafil)**

L9 ANSWER 10 OF 12 MEDLINE DUPLICATE 4
AN 1999071156 MEDLINE
DN 99071156
TI Efficacy and safety of oral sildenafil (Viagra) in men with **erectile** dysfunction caused by **spinal** cord injury.

AU Derry F A; Dinsmore W W; Fraser M; Gardner B P; Glass C A; Maytom M C; Smith M D
CS National Spinal Injury Centre, Stoke Mandeville, UK.
SO NEUROLOGY, (1998 Dec) 51 (6) 1629-33.
Journal code: NZ0. ISSN: 0028-3878.
CY United States
DT (CLINICAL TRIAL)
Journal; Article; (JOURNAL ARTICLE)
(RANDOMIZED CONTROLLED TRIAL)
LA English
FS Abridged Index Medicus Journals; Priority Journals
EM 199903
EW 19990301
AB OBJECTIVE: To evaluate the efficacy and safety of 50-mg doses of sildenafil during a 28-day period in patients with **erectile** dysfunction caused by **spinal** cord injury (cord level range, T6 through L5). BACKGROUND: Sildenafil is an orally active, potent, and selective inhibitor of phosphodiesterase type 5, an important regulator of cyclic guanosine monophosphate in the human corpus cavernosum. METHODS: To be included in this double-blind, placebo-controlled study, all patients had to be able to achieve at least a partial reflexogenic **erectile** response to penile vibratory stimulation. The study utilized a single triangular sequential trial design. A total of 27 patients were randomized to receive 50 mg of sildenafil or placebo, taken orally as required (not more than once daily) approximately 1 hour before sexual activity. RESULTS: After 28 days of treatment, nine of 12 patients (75%) on sildenafil and one of 14 patients (7%) on placebo reported that treatment had improved their **erections** (p=0.0043). Furthermore, eight of 12 patients (67%) on sildenafil and two of 13 patients (15%) on placebo indicated that they wished to continue treatment (p=0.018). A significant improvement in satisfaction with their sex life was reported by patients taking sildenafil (p=0.012). No patients discontinued treatment due to adverse events. CONCLUSION: Oral sildenafil, taken as required (not more than once daily), significantly improves the quality of **erections** and satisfaction with sex life in men with **erectile** dysfunction caused by a **spinal** cord injury between T6 and L5.
TI Efficacy and safety of oral sildenafil (Viagra) in men with **erectile** dysfunction caused by **spinal** cord injury.
AB OBJECTIVE: To evaluate the efficacy and safety of 50-mg doses of sildenafil during a 28-day period in patients with **erectile** dysfunction caused by **spinal** cord injury (cord level range, T6 through L5). BACKGROUND: Sildenafil is an orally active, potent, and selective inhibitor of phosphodiesterase. . . be included in this double-blind, placebo-controlled study, all patients had to be able to achieve at least a partial reflexogenic **erectile** response to penile vibratory stimulation. The study utilized a single triangular sequential trial design. A total of 27 patients were. . . of 12 patients (75%) on sildenafil and one of 14 patients (7%) on placebo reported that treatment had improved their **erections** (p=0.0043). Furthermore, eight of 12 patients (67%) on sildenafil and two of 13 patients (15%) on placebo indicated that they. . . due to adverse events. CONCLUSION: Oral sildenafil, taken as required (not more than once daily), significantly improves the quality of **erections** and satisfaction with sex life in men with **erectile** dysfunction caused by a **spinal** cord injury between T6 and L5.
CT Check Tags: Human; Male; Support, Non-U.S. Gov't
Administration, Oral
Adult
Double-Blind Method
*Enzyme Inhibitors: AE, adverse effects
***Impotence: DT, drug therapy**

***Impotence: ET, etiology**
Middle Age
*Piperazines: AE, adverse effects
Reflex: DE, drug effects
Sexuality
***Spinal Cord Injuries: CO, complications**
RN **139755-83-2 (sildenafil)**

L9 ANSWER 11 OF 12 MEDLINE
AN 1999024309 MEDLINE
DN 99024309
TI Oral sildenafil (Viagra) on trial.
AU van der Linde I
SO SOUTH AFRICAN MEDICAL JOURNAL, (1998 Oct) 88 (10) 1290.
Journal code: U4R. ISSN: 0038-2469.
CY South Africa
DT Journal; Article; (JOURNAL ARTICLE)
LA English
FS Priority Journals
EM 199903
EW 19990303
CT Check Tags: Female; Human; Male
*Enzyme Inhibitors: TU, therapeutic use
Follow-Up Studies
***Impotence: DT, drug therapy**
*Piperazines: TU, therapeutic use
Spinal Cord Injuries: CO, complications
RN **139755-83-2 (sildenafil)**

L9 ANSWER 12 OF 12 HCAPLUS COPYRIGHT 2000 ACS
AN 1999:68946 HCAPLUS
DN 130:231768
TI Pharmacotherapy of male **erectile** dysfunction with sildenafil
AU Kulkarni, S. K.; Reddy, D. S.
CS University Institute of Pharmaceutical Sciences, Panjab University, Chandigarh, 160 014, India
SO Indian J. Pharmacol. (1998), 30(6), 367-378
CODEN: INJPD2; ISSN: 0253-7613
PB Indian Pharmacological Society
DT Journal; General Review
LA English
AB A review with 55 refs. Male **erectile** dysfunction (MED) is a common sexual disorder influenced by psychol., org., phys., endocrine and neurovascular factors. Parasympathetic stimulation activates cholinergic receptors resulting in increased prodn. of nitric oxide and vasoactive peptides which increase the cGMP (cGMP) and thereby increasing vascular smooth muscle relaxation and vasodilation of corpus cavernosum. This causes rigid penile **erection** sufficient for sexual intercourse. However, in **erectile** dysfunction, there is an inability to achieve or maintain a penile **erection**. One of the current approaches in therapies for MED includes elevating levels of cGMP using phosphodiesterase (PDE) inhibitors. Sildenafil is the first orally active, potent and competitive inhibitor of type-5 cGMP-specific PDE enzyme that has been recently approved for the treatment of MED. Sildenafil is a synthetic methylpiperazine deriv. that selectively inhibits PDE in human corpus cavernosum. Sildenafil has demonstrated its effectiveness in **erectile** dysfunction in several preclin. and clin. studies. It is well-tolerated (50-100 mg/day, p.o.) and safe agent for **erectile** dysfunction in patients with diabetes, traumatic **spinal** cord injury, psychol. causes and physiol. disorders. Adverse events reported include transient headache, dyspepsia, flushing, diarrhea and visual disturbance. The discovery of sildenafil has not only resulted in a huge market for drugs, but also unfolded the pathophysiol. of **erectile** dysfunction. However, more controlled clin. studies

are needed to establish the safety of sildenafil in patients with different age groups.

TI Pharmacotherapy of male **erectile** dysfunction with sildenafil

AB A review with 55 refs. Male **erectile** dysfunction (MED) is a common sexual disorder influenced by psychol., org., phys., endocrine and neurovascular factors. Parasympathetic stimulation activates cholinergic.

. . increase the cGMP (cGMP) and thereby increasing vascular smooth muscle relaxation and vasodilation of corpus cavernosum. This causes rigid penile **erection** sufficient for sexual intercourse. However, in **erectile** dysfunction, there is an inability to achieve or maintain a penile **erection**. One of the current approaches in therapies for MED includes elevating levels of cGMP using phosphodiesterase (PDE) inhibitors. Sildenafil is. . . Sildenafil is a

synthetic methylpiperazine deriv. that selectively inhibits PDE in human corpus cavernosum. Sildenafil has demonstrated its effectiveness in **erectile** dysfunction in several preclin. and clin. studies. It is well-tolerated (50-100 mg/day, p.o.) and safe agent for **erectile** dysfunction in patients with diabetes, traumatic **spinal** cord injury, psychol. causes and physiol. disorders. Adverse events reported include transient headache, dyspepsia, flushing, diarrhea and visual disturbance. The discovery of sildenafil has not only resulted in a huge market for drugs, but also unfolded the pathophysiol. of **erectile** dysfunction. However, more controlled clin. studies are needed to establish the safety of sildenafil in patients with different age groups.

ST review sildenafil **erectile** dysfunction

IT **Impotence**
(sildenafil treatment **erectile** dysfunction in men)

IT **139755-83-2**, Sildenafil
RL: ADV (Adverse effect, including toxicity); BAC (Biological activity or effector, except adverse); THU (Therapeutic use); BIOL (Biological study);
USES (Uses)
(sildenafil treatment **erectile** dysfunction in men)

IT 9068-52-4, CGMP Phosphodiesterase
RL: BPR (Biological process); BIOL (Biological study); PROC (Process)
(sildenafil treatment **erectile** dysfunction in men)

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FULL ESTIMATED COST	14.65	22.30

DISCOUNT AMOUNTS (FOR QUALIFYING ACCOUNTS)	SINCE FILE ENTRY	TOTAL SESSION
CA SUBSCRIBER PRICE	-1.67	-1.67

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